

### **REMARKS**

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Currently, claims 82-96 are pending in the present application, including independent claim 82. Independent claim 82, for instance, is directed to a method for simultaneously detecting the presence of at least two metalloproteinases in a chronic wound of a human or an animal. The method comprises collecting a sample of fluid from the chronic wound and exposing the sample to a plurality of target antibodies including a first target antibody that is configured to bind with a first metalloproteinase to form a first target antibody/metalloproteinase complex and a second target antibody that is configured to bind with a second metalloproteinase to form a second target antibody/metalloproteinase complex. The first metalloproteinase is identified by determining the presence or absence of a detectable or measurable manifestation of a first signal element bound to the first target antibody and the second metalloproteinase is identified by determining the presence or absence of a detectable or measurable manifestation of a second signal element bound to the second target antibody.

Support for the new claims can be found throughout the specification and in particular from page 10, line 28 through page 11, line 18, from page 12, line 11 through page 13, line 2, and in Example 1.

In the Office Action, claims 62, 63, 65, 66, 68-81 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement as well as for failure to provide adequate written description. It is respectfully pointed out that claims 62, 63, 65, 66, 68-81 have been cancelled thereby rendering this rejection moot. The cancellation of these claims

should not be considered to reflect any belief of the Applicants as to any lack of patentability of these claims, and Applicants reserve the right to reassert these claims in a continuation application filed under 37 U.S.C. §1.53(b).

In the Office Action, claims 79-81 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sorsa, et al. (U.S. Patent No. 5,736,341) in view of Rowe, et al. (*Anal. Chem.*, **71**, (1999) 3846-3852), and further in view of Stratmann, et al. (*FEBS Letters*, **507** (2001) 285-287), or Brew, et al. (*Biochimica et Biophysica Acta*, **1477** (2000) 267-283) and Sodek, et al. (*MATRIX Supplement No. 1*, (1992) 352-362). In addition, claims 79-81 were rejected under 35 U.S.C. §103(a) as being unpatentable over Trengove, et al. (*Wound Rep. Reg.*, **7:6** (1999) 442-452) in view of Sorsa, et al. and Rowe, et al. and further in view of Stratmann, et al. and Brew, et al. It is respectfully pointed out that claims 79-81 have been cancelled thereby rendering this rejection moot. However, as new claims 82-96 may be construed as sharing certain limitations with cancelled claims 79-81 such as, for instance, simultaneously detecting a plurality of MMPs, Applicants proffer the following remarks.

Applicants respectfully submit that the above-listed references, taken alone or in any combination, fail to disclose or suggest certain limitations of the pending claims. For instance, none of the cited references disclose or suggest a method for simultaneously detecting a plurality of metalloproteinases. As pointed out in the Office Action, neither Trengove, et al., Sorsa, et al., Stratmann, et al., or Brew, et al., or a combination thereof, teach a method for detecting a plurality of metalloproteases.

Moreover, Sorsa, et al. teaches the detection of only one specific MMP, MMP-8, in either the active or pro-form. According to the patent, MMP-8 is the only MMP

detected, as MMP-8 is "the primary cause of gingival tissue destruction in periodontal disease" (col. 9, ll. 47-53). Other MMPs were considered in the patent, but when GCF was examined by Sorsa, et al. for detection of a second MMP via Western blot analysis, "MMP-1 was not detected. MMP-1 was not detected by specific ELISA recording either." While GCF from periodontitis patients was found to contain increased amounts of MMP-8, hardly any immunoreactive fibroblast-type MMP-1 was found. (Col. 17, ll. 45-60.) Hence, Sorsa, et al. teaches that only MMP-8 need be detected in diagnosing periodontitis, and provides no incentive for the detection of multiple MMPs.

Sodek, et al., describes studies of the role certain MMPs play in connective tissue destruction that occurs as a consequence of inflammatory disease, with particular emphasis on the role of collagenase and gelatinase in periodontal disease. Sodek, et al., does not, however, teach a method for detecting a plurality of metalloproteases.

Similarly, Rowe, et al. does not teach a method for detecting a plurality of metalloproteases. Rowe, et al. discloses an array biosensor for simultaneously detecting the presence of different classes of analytes. Specifically, the biosensor of Rowe, et al. simultaneously detects and distinguishes between bacterial (*Bacillus globigii*), viral (MS2 bacteriophage), and protein (staphylococcal enterotoxin B) analytes in a mixture.

The present inventors have discovered that the claimed rapid and accurate detection method allows for the immediate identification of multiple metalloproteinases as well as both the active and pro-forms of a single metalloproteinase. Advantageously, the method may be used to diagnose the *current* condition of the chronic wound, without having to wait several days for the result. As such, more effective treatment

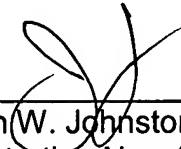
options can be considered as the current condition of a chronic wound can vary rapidly with time. For at least these reasons, Applicants respectfully submit that the present claims patentably define over the prior art of record.

As such, at least for the reasons set forth herein, Applicants respectfully submit that the present application is in complete condition for allowance and favorable action, is therefore requested. Examiner Swope is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

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